

REMARKS

Claims 35, 42, 48, and 49 have been canceled without prejudice or disclaimer. Therefore, claims 33, 36-40, 43-47, and 50-71 are pending in the present application and at issue.

Applicants thank Examiner Rao for stating that the subject matter of claims 36-40, 43-47 and 50-69 is allowable.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 33, 35, 42, 48-49 and 70 under 35 U.S.C. 112

Claims 33, 35, 42, 48-49 and 70 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for a xyloglucanase enzyme that is either 80%, 85%, 90% identical to amino acids 36-559 or 40-559 of SEQ ID NO: 2, 4, or 6. This rejection is respectfully traversed.

It is well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hilzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

Applicants submit that the specification complies with the enablement requirement.

The claimed inventions are drawn to polypeptides having xyloglucanase activity. The claimed xyloglucanases are structurally similar because they are encoded by DNA sequences which hybridize under specified stringency conditions with nucleotides 121-1677 of SEQ ID NOS: 1, 3, or 5, or have amino acid sequences which a high level of identity with amino acids 40-559 of SEQ ID NO: 2, 4, or 6. Thus, the specification provides a precise definition of the claimed polypeptides. Furthermore, the specification contains an extensive disclosure of techniques which are well known in the art and indeed routine for persons of ordinary skill in the art for identifying other nucleotides of the present invention.

The Office alleges that "While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or modifications of nucleotides ..., and the base changes within a nucleic acid's sequence can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited and the result of such modifications is unpredictable." This is respectfully traversed.

This contention may have been true many years ago, however, it is certainly not the case as of the effective filing date of this application. As of February 2000, persons of ordinary skill in the art were able to routinely produce thousands of mutants of SEQ ID NOS: 1, 3 and 5 through mutagenesis and other techniques in a short period of time. Furthermore, at page 16, lines 12-31, the specification discloses how one of ordinary skill in the art could identify essential amino acids in the sequences of SEQ ID NOS: 2, 4, and 6. Thus, one of ordinary skill in the art can predict which modifications, if any, would result in a loss of the desired activity/utility.

We draw the Examiner's attention to *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976). In *Angstadt*, the claimed process of preparing hydroperoxides used a metal salt complex as a catalyst. The specification disclosed catalysts that worked and some that gave little or no yield of hydroperoxides. The claims were rejected for lack of enablement, specifically as requiring undue experimentation to find useful catalysts. This rejection was reversed by the CCPA.

In holding that the claims did satisfy 35 USC 112, the Court observed, 190 U.S.P.Q. at 218:

We cannot agree with the board that appellants' disclosure is not sufficient to enable one of ordinary skill in the art to practice the invention without undue experimentation. We note that many chemical processes, and catalytic processes particularly, are unpredictable, [citation omitted] and that the scope of enablement varies inversely with the degree of unpredictability involved, [citation omitted]. That this particular process is unpredictable is demonstrated further by appellants in their specification. Appellants have disclosed forty examples; one of these examples yields no hydroperoxides in the final product. Also, appellants have expressly indicated in their specification that some of these organometallic complex catalysts 'yield *** no hydroperoxides in the final product.'

Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with 'thousands' of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage

inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid 'literal' infringement of such claims by merely finding another analogous catalyst complex which could be used in 'forming hydroperoxides.'

This admonition applies with equal force to the present application, which exemplifies three xyloglucanases and discloses numerous Examples illustrating their use. To require more would fly in the face of the *Angstadt* holding.

The Court, 190 USPQ at 218, recognized that some experimentation might be necessary for the skilled worker to select non-exemplified catalysts for use:

Appellants have, in effect, provided those skilled in this art with a large but finite list of transition metal salts from which to choose in preparing such a complex catalyst. Appellants have actually carried out 40 runs using various transition metal salts and hexaalkylphosphoramides. If one skilled in this art wished to make and use a transition metal salt other than those disclosed in appellants' 40 runs, he would merely read appellants' specification for directions how to make and use the catalyst complex to oxidize the alkylaromatic hydrocarbons, and could then determine whether hydroperoxides are, in fact, formed. The process discovered by appellants is not complicated, and there is no indication that special equipment or unusual reaction conditions must be provided when practicing the invention. One skilled in this art would merely have to substitute the correct mass of a transition metal salt for the transition metal salts disclosed in appellants' 40 runs. Thus, we have no basis for concluding that persons skilled in this art, armed with the specification and its 40 working examples, would not easily be able to determine which catalyst complexes within the scope of the claims work to produce hydroperoxides and which do not.

However, while some experimentation might be necessary, as long as the experimentation was not "undue experimentation," the claims would not violate 35 USC 112, *Angstadt, Id.*:

Since appellants have supplied the list of catalysts and have taught how to make and how to use them, we believe that the experimentation required to determine which catalysts will produce hydroperoxides would not be undue and certainly would not 'require ingenuity beyond that to be expected of one of ordinary skill in the art.' (Emphasis added).

As in *Angstadt*, the present application identifies three xyloglucanases of the present invention. While some experimentation might be necessary to identify other non-exemplified xyloglucanases, such experimentation would require carrying out a simple process without special equipment or unusual reaction conditions, as in *Angstadt*. This experimentation, if

required, "would not be undue and certainly would not require ingenuity beyond that expected of one of ordinary skill in the art." (*Angstadt*, 190 U.S.P.Q. at 218). Certainly, there is no evidence of record to the contrary.

However, in order to advance prosecution, the subject matter of allowed claims 36, 43 and 50 has been incorporated into claim 33.


For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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